

28. (Previously presented) A method for transdermal delivery of a drug comprising the steps of
- (A) a step of providing a composition comprising
 - (i) a copolymer comprising
 - (a) at least one A monomer selected from the group consisting of an alkyl acrylate containing 4 to 12 carbon atoms in the alkyl group and an alkyl methacrylate containing 4 to 12 carbon atoms in the alkyl group; and
 - (b) pyrrolidonoethyl acrylate; and
 - (ii) a drug in an amount such that the composition delivers a therapeutically effective amount for the indication being treated; and
 - (B) a step of applying the composition to an external part of the human body for a period sufficient to achieve the desired therapeutic result.
29. (Original) A pressure sensitive tape comprising a backing and a composition according to claim 1, the composition being coated on at least a portion of a surface of the backing.
30. (Previously presented) A pressure sensitive adhesive copolymer comprising
- (a) at least one A monomer selected from the group consisting of an alkyl acrylate containing 4 to 12 carbon atoms in the alkyl group and an alkyl methacrylate containing 4 to 12 carbon atoms in the alkyl group; and
 - (b) pyrrolidonoethyl acrylate.
31. (New) The composition of claim 1 wherein the A monomer contains from about 40% to about 95% by weight.

Remarks

Applicants amend claim 31 to more completely claim the present invention per Examiner's request. The claim amendment is offered to correct certain formal defects in the claim as filed and is offered free of any intent to narrow the scope of what Applicants' consider as

their invention. Support for the amendments may be found throughout the specification as filed, including the documents and references cited and incorporated therein.

Claim Rejections With Respect to the '902 Reference

Claims 1-30 stand rejected under 35 U.S.C. §103(a) as rendered obvious over the disclosure of U.S. Patent 3,966,902 ('902). The Examiner argues that the '902 reference discloses a composition comprising a drug in a polymer carrier comprising pyrrolidonoethyl methacrylate and monomer comprising carboxylic acid with an inherent number of carbon atoms for the monomer. The Examiner argues that it would have been obvious to replace PyEMA with PyEA since "both are adhesives with a reasonable expectation of having a composition with improved adhesiveness." Additionally, the Examiner indicates that the number of carbon atoms is inherent.

Applicants respectfully traverse the rejection. The '902 reference teaches a drug in polymer carrier with complexing agents of aluminum, zinc, and/or zirconium. The number of carbon atoms is not inherent for the monomer. Alkyl acrylate and alkyl methacrylate can have a range of carbon atoms from 1 to more than twenty with methyl methacrylate (having 1 carbon) being the most common alkyl methacrylate.

Furthermore, the '902 reference does not teach the generic concept of using alkyl acrylate in combination with a pyrrolidone monomer. Instead the '902 reference teaches polymer complex carriers and discloses hydrophilic monomers containing amino groups as functional groups. The alkyl group of the '902 reference suggests any number of carbon atoms (such as 1 to 30), but it does not specifically suggest 4-12 carbon atoms, which is a range most useful for pressure sensitive adhesive properties. The '902 reference fails to suggest pressure sensitive adhesive properties. There is a critical performance difference between an alkyl acrylate having any number of carbon atoms and one having only 4 to 12 carbon atoms, namely, satisfactory pressure sensitive adhesive performance.

The Examiner suggests replacing PyEMA with PyEA since "both are adhesives," to produce a reasonable expectation of having a composition with improved adhesiveness. Again, Applicants respectfully traverse. PyEMA and PyEA are not adhesives. In fact, they may be used as comonomers in pressure sensitive adhesives. There is no suggestion in the '902 reference that suggests pressure sensitive adhesive properties of a purported PyEMA, alkyl acrylate copolymer.

For at least these reasons, Applicants respectfully request that the rejected claims 1-30 are patentable under 35 U.S.C. §103(a).

Claim Rejections With Respect to the '902 Reference in view of the '996 or '229 References

Claims 1-30 stand rejected under 35 U.S.C. §103(a) as rendered obvious over the disclosure of U.S. Patent 3,966,902 ('902) in view of US 6,193,996 ('996) or WO 96/08229 ('229). The Examiner argues that the '902 reference discloses a composition comprising a drug in a polymer carrier comprising pyrrolidonoethyl methacrylate and monomer comprising carboxylic acid with an inherent number of carbon atoms for the monomer. Again, the Examiner also indicates that the number of carbon atoms is inherent. The Examiner argues that the '996 reference teaches a pressure sensitive adhesive comprising a copolymer of one or more alkyl acrylates or (meth)acrylates containing 4-12 carbon atoms and one or more hydrophilic monomers. Finally, the Examiner argues that the '229 reference discloses a transdermal drug delivery device comprising a pressure sensitive adhesive comprising copolymers and monomers. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to provide the adhesive composition of '902 and combine it with the monomers of the '996 and add the copolymers of the '902.

Applicants respectfully traverse the rejection. Applicants point out that in parallel with the discussion above, the number of carbon atoms is not inherent for the monomer for Applicant's invention. Alkyl acrylate and alkyl methacrylate can have a range of carbon atoms from 1 to more than twenty with methyl methacrylate (having 1 carbon) being the most common alkyl methacrylate.

The alkyl acrylates in the '902 reference are mentioned as one of several different types of materials that can be incorporated as non-functional parts of the polymer complex carriers. However, the '902 reference fails to teach that alkyl acrylates are useful as polymer complex carriers, but rather that they can be included with the functional parts of the invention without negating that functionality. That teaching or lack thereof, would not reasonably suggest to one skilled in the art that the '906 reference could be combined with alkyl acrylate PSA art with any reasonable expectation of success.

Applicants note that the pyrrolidone derivative of the '996 reference is a permeation enhancer added to an adhesive copolymer. The pyrrolidone derivative is not part of the adhesive copolymer itself as in the present invention. It is well known in the art that the N-vinyl-2-pyrrolidone (or NVP) is known as a pressure sensitive adhesive monomer (see U.S. Patent Application 4,323,557 (Rosso), also noted in application). The '229 reference does not disclose the general class of pyrrolidones. The reference only discloses NVP which does not cure the defect of the '902 reference.

Applicants submit that there is no pressure sensitive adhesive composition disclosed by '902, so therefore there would be motivation to combine the '996 or '229 references with the '902 reference. Even if the references were to be combined, there would be no expectation of achieving satisfactory pressure sensitive adhesive properties. Although the '996 and '229 references are quite expansive with regards to describing possible co-monomers that may be useful in acrylate copolymer pressure sensitive adhesives, they are silent as to PyEA, PyEMA, or pyrrolidones as a class of B-monomers. Therefore there would no motivation to combine one particular type of copolymer from the '902 reference with monomers and macromonomers from the '996 and '229 references that would produce a satisfactory pressure sensitive adhesive.

For at least these reasons, Applicants respectfully request that the rejected claims 1-5, 7-18, and 25-30 are patentable under 35 U.S.C. §103(a). Furthermore, the secondary references do not cure the defects of the '902 reference to render the present claims obvious.

Claim Rejections With Respect to the '902 Reference in view of the '996 or '229 References and Further in View of the US 2002/0110585 Reference

Claims 19-24 stand rejected under 35 U.S.C. §103(a) as rendered obvious over the disclosure of U.S. Patent US 3,966,902 ('902) in view of US 6,193,996 ('996) or WO 96/08229 ('229) and further in view of the US 2002/0110585 ('585) Reference. The Examiner lodges the same argument for the rejection of the above claims based on the '902, '996, and '229 references. Additionally, the Examiner argues that the '585 reference in combination with the above mentioned references renders the claims obvious.

Applicants respectfully traverse the rejection. Applicants submit that the '585 reference does list chlorhexidine and iodine as part of its exhaustive list of drugs to be delivered to the

copolymer reservoir. However, this disclosure fails to demonstrate any particular expectation of success for using either of these drugs with this specific copolymer. The '585 reference does not cure the defects of the '902 reference in view of the '966 or '229 references. Claims 19-24 are therefore not obvious under 35 U.S.C. §103(a).

In view of the arguments and amendments offered herein, Applicants respectfully submit that the Examiner's grounds for objection and rejection are overcome and respectfully solicit reconsideration and withdrawal of the rejections and allowance of the application.

Respectfully submitted,

Date

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By:

Robert W. Sprague, Reg. No. 30,497
Telephone No.: (651) 733-4247

Office of Intellectual Property Counsel
3M Innovative Properties Company
Facsimile No.: 651-736-3833